

# Complementary and Alternative Medicine

Focus on Research and Care

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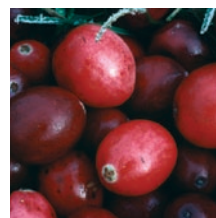
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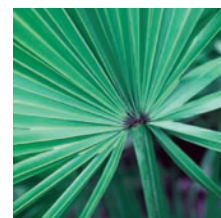


## Urinary Tract Conditions: Examining the Evidence on Cranberry and Saw Palmetto

Patients with urinary tract infections (UTIs) or benign prostatic hyperplasia (BPH) often ask health care providers about using complementary and alternative medicine (CAM) to relieve symptoms or prevent recurrences. There are many reasons that CAM therapies may appeal to these patients—for example, if they are concerned about the side effects or costs of prescription medicines; worried about antibiotic resistance (in the case of UTI); concerned about the potential effects of more invasive treatments on sexual function or continence (in the case of BPH); or seeking “natural” approaches to treating these conditions.



Cranberry



Saw palmetto

### Urinary Tract Infections

UTIs occur at all ages and in both genders, although the incidence is 50 times higher in women. Up to one-third of women have at least one recurrence after their first episode. In men, UTIs are uncommon before age

*continued on 6*



## NCCAM Celebrates a Decade of Discovery and Achievement

The year was 1999. The new millennium and “Y2K” were imminent,

and Congress had just created the National Center for Complementary and Alternative Medicine at the National Institutes of Health, bringing scientific rigor to the study of complementary and alternative medicine.

Ten years later, interest in CAM and integrative medicine is strong. NCCAM Director Josephine P. Briggs, M.D., reflects on a decade of discoveries

and achievements—from bench to bedside—and the impact of NCCAM’s investments.

**OUR MISSION** The National Center for Complementary and Alternative Medicine is dedicated to exploring complementary and alternative healing practices in the context of rigorous science; training scientists to study complementary and alternative medicine; and disseminating authoritative information to the public and professionals.

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NCCAM Newsletter Editorial Office  
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## Conference on CAM and Integrative Medicine Highlights Collaborations, Progress

Ginger. Meditation. Chinese herbal formulas. Placebo. Acupuncture. Health care economics. The relationship between patients and practitioners. Research methodology.

These were some of the topics at the fourth North American Research Conference on Complementary and Integrative Medicine, held May 12-15 in Minneapolis. "Collaboration To Promote Scientific Discovery and Health" was the theme.

Close to 800 attendees from 24 countries came together to share information and perspectives on complementary, alternative, and integrative medicine research.

The conference was cofunded by NCCAM and sponsored by the Consortium of Academic Health Centers for Integrative Medicine (CAHCIM), a membership organization whose mission is to advance the principles and practices of integrative health care within academic institutions. Twenty-six other organizations representing many professional disciplines and fields served as "participating organizations."

Jack Killen, M.D., Deputy Director of NCCAM, served on the planning committee. "As were the two earlier conferences in this series," Dr. Killen said, "this conference was fascinating and memorable. It was a terrific opportunity for networking and collaboration across disciplines, fields, and organizations.

"We at NCCAM were gratified to hear attendees' comments," he continued, "on just how far the science of CAM has come in the past 5 and 10 years—much of that progress a direct result of the rigorous research, the training and career development, and the outreach that the Center has funded."



Victor S. Sierpina, M.D.

Victor Sierpina, M.D., the chair of CAHCIM, noted the attendance of young investigators. "Their creativity, enthusiasm, and energy were most impressive, as were the sophistication of methodologies, technologies, and the kinds of nuanced questions posed.... Support from NCCAM and NIH has lent credibility and impetus to the field in major ways." He also commented, "[We saw] that the underlying mechanisms of such areas as placebo, acupuncture, and mind-body practices are demonstrable... [and] clinical outcome studies on integrative practices are going to be the next major step in having such practices integrated into our health care systems."

Abstracts summarizing over 300 presentations and posters may be browsed for free at [www.cahcimabstracts.com](http://www.cahcimabstracts.com). The conference's main Web site is [www.imconsortium-conference.org](http://www.imconsortium-conference.org).



## From the Director

A key theme in this issue—and at NCCAM throughout 2009—is our 10th anniversary. It is a time to look back, to evaluate where we are now, and to plan ahead. The formal part of this process is the development of a strategic plan to be released next year.

The fields of CAM and integrative medicine are incredibly rich, broad, and diverse. This is both a gift and a challenge. During its first decade, NCCAM's portfolio of research reflected a wide range of breadth and diversity.

As we embark on our second decade, a new era, we seek to refine our portfolio to maximize the impact of the Center's programs and activities upon the public health and public good.

In setting priorities, we currently identify four factors as important considerations:

- Use by the public
- Scientific promise
- Potential to change health or health care practices
- Amenability to rigorous scientific inquiry.

One major strategic planning event took place on September 10, 2009, a workshop that was part of our national advisory council's fall meeting. Thought leaders from CAM and conventional medicine, as well as researchers and consumer representatives, provided valuable insight into areas of focus for the future. Position papers emerged from the workshop that are posted at [nccam.nih.gov/about/plans/2010](http://nccam.nih.gov/about/plans/2010). We invite, and would appreciate, your comments on them.

It is important to us that our research portfolio reflect awareness of and sensitivity to the questions that our stakeholders face. For example, if you are a health care provider, what are some of the difficult clinical decisions you face in which having more evidence would be useful? Are there areas in which you see unsolved questions? Is NCCAM's information useful to you? How can we make it even more useful?

In closing, I am pleased to note that we launch our next decade under the leadership of Francis S. Collins, M.D., Ph.D., the new Director of NIH. Among his many achievements, Dr. Collins has been an inspired Director of NIH's National Human Genome Research Institute. My colleagues and I at NCCAM look forward to working with Dr. Collins as we pursue medical discoveries to improve the health of all Americans.

*Josephine P. Briggs, M.D.  
Director*

## NCCAM's 10th Anniversary Research Symposium: Exploring the Science of Complementary and Alternative Medicine

Tuesday, December 8, 9:00 a.m.-4:15 p.m. Eastern time

Masur Auditorium, NIH, Bethesda, Maryland

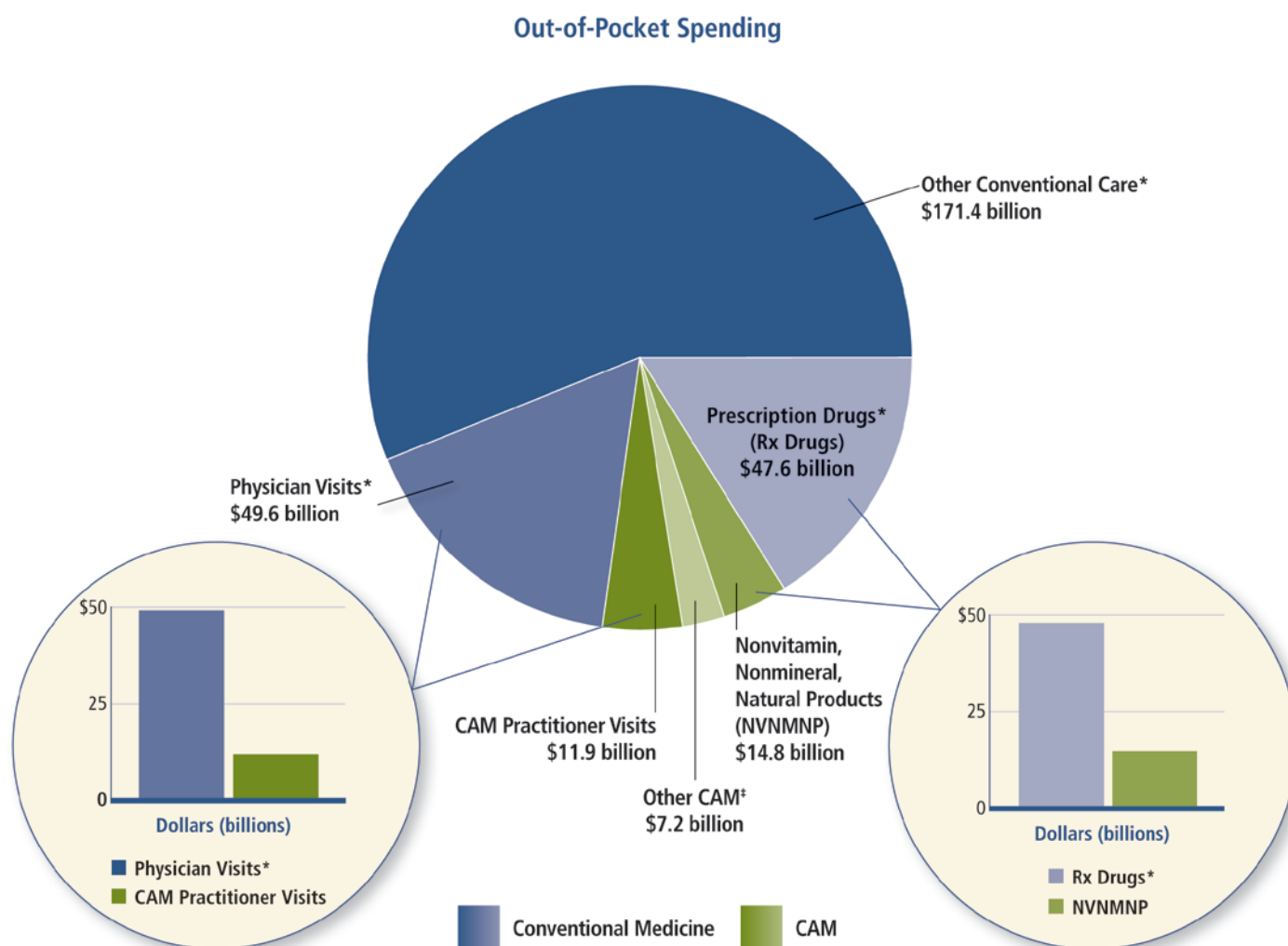
Webcast (live and archived) at [videocast.nih.gov](http://videocast.nih.gov)

Details at [nccam.nih.gov/news/events/anniversary\\_symposium.htm](http://nccam.nih.gov/news/events/anniversary_symposium.htm)



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## New Survey Details Billions Americans Spend on CAM



\* National Health Expenditure Data for 2007. U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services Web site. Accessed at: [http://www.cms.hhs.gov/NationalHealthExpendData/02\\_NationalHealthAccountsHistorical.asp#TopOfPage](http://www.cms.hhs.gov/NationalHealthExpendData/02_NationalHealthAccountsHistorical.asp#TopOfPage) on June 25, 2009.  
 ‡ Other CAM includes yoga, tai chi, qi gong classes; homeopathic medicine; and relaxation techniques.

New data from the 2007 National Health Interview Survey show that Americans spent an estimated \$33.9 billion out-of-pocket on CAM products and services in 2007, which made up 11.2 percent of all out-of-pocket health care spending. Of the amount spent on CAM, about two-thirds (\$22.0 billion) was for self-care in the form of CAM products, classes, and materials—especially natural products (\$14.8 billion)—and about one-third for visits to CAM practitioners (\$11.9 billion). For the full survey report, a fact sheet, and downloadable graphics, visit [nccam.nih.gov/news/camstats/costs/](http://nccam.nih.gov/news/camstats/costs/).

**Reference:** Nahin RL, Barnes PM, Stussman BJ, and Bloom B. Costs of Complementary and Alternative Medicine (CAM) and Frequency of Visits to CAM Practitioners: United States, 2007. *National Health Statistics Report; no 18*. Hyattsville, MD: National Center for Health Statistics. 2009.



## An Interview With Wendy Weber, N.D., Ph.D., M.P.H.

**W**endy Weber, N.D., Ph.D., M.P.H., is a new program officer in NCCAM's Division of Extramural Research. Previously, Dr. Weber was a research associate professor at Bastyr University and supervised the Attention Deficit/Hyperactivity Disorder (ADHD) Wellness Clinic at the Bastyr Center for Natural Health.

Dr. Weber's research includes the study of herbal treatments for the common cold and ADHD, including the effects of echinacea on upper respiratory tract infections in children, naturopathic treatment of children, and neuropsychological function in ADHD. Her articles have appeared in several peer-reviewed journals, including the Journal of the American Medical Association. Dr. Weber received her N.D. (Doctor of Naturopathic Medicine) degree from Bastyr University and her Ph.D. in epidemiology and M.P.H. from the University of Washington. She is the first naturopathic physician to serve as a program officer at NCCAM.

### What brought you to NCCAM, and what areas are in your research portfolio?

My decision to work at NCCAM stems from my interest in shaping the future of CAM research. As a researcher in the extramural community, I conducted my studies and mentored junior researchers, post-doctoral fellows, and students.

At NCCAM, I have the opportunity to identify research gaps and develop a program of research by encouraging extramural scientists to submit applications to fill these gaps. My current portfolio includes health services research; traditional medical systems; mind-body and manipulative therapies for pediatric conditions; and clinical studies in mental health disorders, cardiovascular diseases, and gastrointestinal disorders.

### The public is spending a considerable amount out-of-pocket on CAM for self-care, wellness, and prevention. Can you give us a brief idea of how naturopathy sees these topics?

Naturopathic physicians base their practice on a set of six principles founded on medical tradition. Self-care, wellness, and prevention are all aspects of the naturopathic principles. One is that the doctors must

also be educators, particularly when it comes to teaching patients how to live a healthy life by eating well, exercising appropriately, and incorporating relaxation into their lives. Patient education includes encouraging self-responsibility for a healthy lifestyle.

Naturopathic physicians discuss risk factors, family history, and environmental exposures with patients in an effort to develop an individualized plan to prevent illness and encourage optimal wellness. For example, a patient with a parent who experienced a heart attack before the age of 50 might be encouraged to reduce the risks of heart disease with a diet rich in omega-3 fatty acids and fiber for triglyceride and cholesterol management, maintaining a healthy weight through exercise and a balanced diet, and using stress reduction techniques to aid in blood pressure control.

### Tell us a little about your practice as a naturopathic physician.

In Seattle, I maintained an active clinical practice in addition to my research and teaching. I primarily treated children and adolescents with mental health disorders (ADHD, anxiety, and depression), abdominal pain, or skin problems. I really enjoyed working with families to help children make



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Wendy Weber, N.D., Ph.D., M.P.H.

healthier nutritional choices, which in numerous cases alleviated the presenting condition. I found that pediatric patients responded well to dietary supplementation as needed, or short-term use of custom herbal teas. Since relocating to the east coast, I have not set up a practice but hope to find a way to continue to work with patients.

### In your practice, how did you work with conventionally trained health care providers?

I always tried to open a direct line of communication. Some of my most successful collaborations were as a result of picking up the phone and talking to the provider about the patient we shared. It was important to communicate my desire to not interfere with the treatment course already prescribed for the patient. I would tell the clinician about the treatments I was considering and if there were any known interactions with the medications the patient was currently taking. By proactively addressing the most common concern of potential interactions, I was able to develop a good working relationship with the clinician and would often receive additional referrals.

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50 and often are caused by an underlying disorder, such as a urinary or kidney stone or an enlarged prostate. UTIs in older adults may be caused by a condition such as incontinence or incomplete emptying of the bladder.

UTIs are the second most common bacterial infection after respiratory infections. In 2000 in the United States, about 11 million outpatient visits, 1.7 million emergency room visits, 367,000 hospitalizations, and \$3.5 billion in health care expenditures were attributed to UTIs in adults. *E. coli* is most often the cause, but other microorganisms may also play a role.



## CRANBERRY

The natural product that is most used for UTI, and on which there is the most evidence, is cranberry (*Vaccinium macrocarpon*). In a 2007 national survey on Americans' use of CAM, among those who used natural products, cranberry was used by 6 percent (which translates to about 1.6 million people).

The mechanism of action of cranberry is not fully understood, but basic research has yielded findings that may explain its potential benefit in UTIs, such as the suggestions that:

- Proanthocyanidins unique to cranberry inhibit the ability of bacteria to adhere to the surface membrane of host cells in the urinary tract
- Cranberry has anti-inflammatory and antioxidant activity.

An early theory, that cranberry inhibits bacteria replication through acidifying the urine, has been largely discredited.

Proanthocyanidins are molecules that help create intense color in fruits and vegetables and are thought to have antioxidant properties.

## Snapshots of the Evidence

### Practice Guidelines

The American College of Obstetricians and Gynecologists (ACOG) released an evidence-based clinical practice guideline in 2008 on uncomplicated acute bacterial cystitis in nonpregnant women. Among ACOG's recommendations are to use antibiotics both as first-line therapy and for prophylactic or intermittent treatment. ACOG notes that drinking cranberry juice has been shown to decrease recurrence of symptomatic UTIs, although the optimal length of treatment and concentration of juice still need to be determined.

### Systematic Reviews/Meta-Analyses

Two systematic reviews/meta-analyses on cranberry from the Cochrane Collaboration concluded the following:

- A 2008 review on cranberry to **prevent** recurrent UTIs (updated from 2004) included 10 randomized or quasi-randomized clinical trials. Most (7) studied cranberry in the form of juice, and 4 studied tablets (1,049 participants in total). The review found "some evidence" that cranberry juice may decrease the number of symptomatic UTIs over a 12-month period compared with placebo/control, especially in women with recurrent UTIs. Applicability to other groups was less certain. The review noted uncertainty as to what the optimum dosage or form is for cranberry therapy; a lack of standardization in available cranberry products; a lack of clarity as to whether juice and capsules/tablets are bioequivalent; and high drop-out rates.
- A 2009 review on cranberry to **treat** UTIs concluded that there is no good-quality evidence on this question.

### Other Reports

The scientific literature also includes laboratory and animal studies as well as clinical trials. Although some findings suggest promise, it is difficult to compare cranberry products across studies. Many of these studies have methodological issues such as:

- Not being randomized or controlled
- Being small in size
- Having quality issues in design or reporting
- Using products that are not standardized.

Research on cranberry for urinary tract conditions is ongoing, including in NCCAM-supported studies using well-standardized, research-grade cranberry products.

### Safety

Cranberry appears to be generally well tolerated in appropriate food amounts. High doses can cause gastrointestinal symptoms. Some commercial products are high in calories. There is indication that long-term use in high amounts might be contraindicated in persons at risk for uric-acid kidney stones. Safety data on long-term use are needed. General cautions that apply to the use of dietary supplements—for example, that product consistency and purity can vary, and that they can interact with drugs and/or other supplements—apply here. For more side effect and safety information, go to [nccam.nih.gov/health/cranberry/](http://nccam.nih.gov/health/cranberry/).

### Benign Prostatic Hyperplasia

BPH is common in men but rarely produces symptoms before age 40. Not all men with BPH have symptoms. The cause of BPH is not well understood but is thought to be connected with hormones, such as the levels of

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# Get the Facts

## Information for Consumers

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## Cranberry



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Cranberry

This fact sheet provides basic information about cranberry—common names, uses, potential side effects, and resources for more information. Cranberries are the fruit of a native plant of North America. These red berries are used in foods and in herbal products.

**Common Names**—cranberry, American cranberry, bog cranberry

**Latin Name**—*Vaccinium macrocarpon*

### What It Is Used For

- Historically, cranberry fruits and leaves were used for a variety of health problems, such as wounds, urinary disorders, diarrhea, diabetes, stomach ailments, and liver problems.
- Recently, cranberry products have been used in the hope of preventing or treating urinary tract infections or *Helicobacter pylori* infections that can lead to stomach ulcers, or to prevent dental plaque. Cranberry has also been reported to have antioxidant and anticancer activity.

### How It Is Used

The berries are used to produce beverages and many other food products, as well as dietary supplements in the form of extracts, teas, and capsules or tablets.

### What the Science Says

- Some studies testing cranberry products for their ability to prevent urinary tract infections have shown promise. These studies have generally been small in size, and some were not randomized or

controlled; therefore, the results are not conclusive.

- Cranberry products have not been adequately tested to see if they can be used to help treat an existing urinary tract infection.

- Research shows that components found in cranberry may prevent bacteria, such as *E. coli*, from clinging to the cells along the walls of the urinary tract and causing infection. However, the mechanism of action of cranberry is not fully understood.

- NCCAM, the National Institute of Diabetes and Digestive and Kidney Diseases, and the National Institute for Dental and Craniofacial Research are funding studies to understand whether and how cranberry might work to:

- ☐ Prevent urinary tract infection
- ☐ Prevent the formation of dental plaque.

### Side Effects and Cautions

- Eating cranberry products in food appears to be safe, but drinking excessive amounts of juice could cause gastrointestinal upset or diarrhea.

- People who think they have a urinary tract infection should see a health care provider for proper diagnosis and treatment. Cranberry products should not be used to treat infection.

- Tell your health care providers about any complementary and alternative practices you use. Give them a full picture of what you do to manage your health. This will help ensure coordinated and safe care.

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### More Information

You can learn more about cranberry from NCCAM by viewing the expanded version of this fact sheet at [nccam.nih.gov/health/cranberry/](http://nccam.nih.gov/health/cranberry/) or ordering a printed version from the NCCAM Clearinghouse. The expanded fact sheet includes selected references and additional resources.

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The NCCAM Clearinghouse provides information on CAM and NCCAM, including publications and searches of Federal databases of scientific and medical literature. Please note that NCCAM does not provide medical advice, treatment recommendations, or referrals to practitioners.

## Research Spotlight



### Cranberry Juice Does Not Interfere With Two Antibiotics for UTIs

About 50 to 60 percent of women are diagnosed with a urinary tract infection (UTI) at least once during their lifetime. Many experience multiple recurrences. Cranberry juice, a popular home remedy for UTI, is often taken along with low-dose antibiotics as a preventive measure. Because little is known about the potential of cranberry juice to interact with drugs, NCCAM-funded researchers at the University of Washington studied cranberry's effects on two antibiotics frequently prescribed for UTI: amoxicillin and cefaclor.

Two parallel studies were conducted, one for amoxicillin and one for cefaclor. In each study, 18 healthy women took a single oral dose of the antibiotic, with either water or cranberry juice cocktail. The procedure was repeated after a week, in a "crossover" design that allowed researchers to evaluate cranberry juice in each participant. The drugs were tested at commonly prescribed dosages: 500 mg for cefaclor in one study; and 500 mg, as well as 2 g, for amoxicillin in the other study. Participants drank 8 ounces of juice or water with amoxicillin, 12 ounces with cefaclor; those who drank juice also drank it twice daily for 2 days before the treatment, to approximate real-life

consumption. Researchers took blood and urine samples at 2-hour intervals for 6 to 8 hours after treatment, and then tested drug concentrations at each point.

The data showed that cranberry juice did not significantly affect either antibiotic's oral absorption or renal clearance (i.e., how completely the body processed the drugs in the intestine and kidneys). Absorption took somewhat longer with cranberry juice, but the delay was small, and the total amount of antibiotic absorbed was not affected.

Based on these results, the researchers concluded that cranberry juice cocktail, consumed in usual quantities, is unlikely to change the effects of these two antibiotics on UTIs. They noted that the same may or may not be true of other antibiotics, or when people who take antibiotics also drink a large quantity of concentrated cranberry juice.

#### Reference

Li M, Andrew MA, Wang J, et al. Effects of cranberry juice on pharmacokinetics of beta-lactam antibiotics following oral administration. *Antimicrobial Agents and Chemotherapy*. 2009;53(7):2725-2732.



# Get the Facts

## Information for Consumers

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## Saw Palmetto



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Saw palmetto

This fact sheet provides basic information about the herb saw palmetto—common names, uses, potential side effects, and resources for more information. Saw palmetto is a small palm tree native to the eastern United States. Its fruit was used medicinally by the Seminole Tribe of Florida.

**Common Names**—saw palmetto, American dwarf palm tree, cabbage palm

**Latin Names**—*Serenoa repens*, *Sabal serrulata*

### What It Is Used For

- Saw palmetto is used mainly for urinary symptoms associated with an enlarged prostate gland (also called benign prostatic hyperplasia, or BPH).
- Saw palmetto is also used for other conditions, including chronic pelvic pain, bladder disorders, decreased sex drive, hair loss, and hormone imbalances.

### How It Is Used

The ripe fruit of saw palmetto is used in several forms, including ground and dried fruit or whole berries. It is available as a liquid extract, tablets, capsules, and as an infusion or a tea.

### What the Science Says

- Several small studies suggest that saw palmetto may be effective for treating BPH symptoms.

■ In 2006, a large study of moderate-to-severe BPH found no improvement with saw palmetto versus placebo. NCCAM cofunded the study with the National Institute of Diabetes and Digestive and Kidney Diseases.

■ There is not enough scientific evidence to support the use of saw palmetto for reducing the size of an enlarged prostate or for any other conditions.

■ Saw palmetto does not appear to affect readings of prostate-specific antigen (PSA) levels. The PSA test is used to screen for prostate cancer and to monitor patients who have had prostate cancer.

### Side Effects and Cautions

- Saw palmetto may cause mild side effects, including stomach discomfort.
- Some men using saw palmetto have reported side effects such as tender breasts and a decline in sexual desire.
- Tell your health care providers about any complementary and alternative practices you use. Give them a full picture of what you do to manage your health. This will help ensure coordinated and safe care.

### More Information

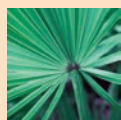
You can learn more about saw palmetto from NCCAM by viewing the expanded version of this fact sheet at [nccam.nih.gov/health/palmetto/](http://nccam.nih.gov/health/palmetto/) or ordering a printed version from the NCCAM Clearinghouse. The expanded fact sheet includes selected references and additional resources.

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## Research Spotlight



### Study Shows Saw Palmetto Extract Does Not Improve BPH Symptoms

**S**aw palmetto is widely used by men for urinary symptoms caused by benign prostatic hyperplasia (BPH, also known as enlarged prostate)—a common condition associated with aging. The evidence of saw palmetto for BPH has been inconclusive because the trials have had design limitations (small samples, short duration, and inadequate outcome measures and blinding procedures). To address these limitations and evaluate safety and efficacy, a study cofunded by NCCAM and the National Institute of Diabetes and Digestive and Kidney Diseases used a randomized, double-blind design to look at the effects of a saw palmetto extract over 1 year in a large sample of men with BPH. The study was conducted by researchers from the University of California, San Francisco; and the San Francisco Veterans Affairs Medical Center.

In the study, 225 men over age 49 who had moderate-to-severe symptoms of BPH were randomly assigned to receive either saw palmetto extract (a 160-mg capsule taken twice daily) or a placebo for 12 months. The saw palmetto product used was a proprietary carbon dioxide extract selected by an NCCAM advisory committee, and was manufactured for the study in a single batch

and analyzed for quality consistency. The treatment regimen was the same as that used in most prior clinical trials.

The study found no significant differences between the saw palmetto and placebo groups in the two primary outcome measures (scores on the American Urological Association Symptom Index for BPH, and maximal urinary flow rate) or in secondary measures (prostate size, residual urinary volume after voiding, quality of life, and serum prostate-specific antigen levels). The incidence of adverse events during the study period was also similar in the two groups.

The researchers concluded that 160 mg of this saw palmetto extract given twice daily for 1 year does not improve lower urinary tract symptoms caused by BPH. They noted that the extract's dose may not have been sufficient to produce a measurable result—a possibility they could not fully address because the active ingredient in saw palmetto, if one exists, is not known.

#### Reference

Bent S, Kane C, Shinohara K, et al. Saw palmetto for benign prostatic hyperplasia. *New England Journal of Medicine*. 2006;354(6):557-565.

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dihydrotestosterone and/or estrogen. More than half of men aged 50 or older, and as many as 90 percent of men in their 70s and 80s, have symptoms of BPH. As a condition, it is estimated to account for at least 1.7 million office visits to physicians and over \$4 billion in health care costs per year in the United States. As the population ages and life expectancy continues to rise, the incidence and prevalence of BPH are expected to rise as well.

Lower urinary tract symptoms (LUTS) associated with BPH can range from mild to very bothersome, and include frequency or urgency of urination, nocturia, slow stream, and leakage. Urinary retention associated with BPH potentially can lead to complications, although these are less common, such as UTI, or bladder or kidney damage. Having BPH is not a risk factor for prostate cancer, although both can occur simultaneously.

An increasing number of men are treating their BPH symptoms with botanical preparations sold over-the-counter, using them as individual agents or in combination with prescribed drugs. A 2006 estimate placed the sales of botanicals marketed for BPH symptoms at over \$6 billion per year.

## SAW PALMETTO

Saw palmetto (*Serenoa repens*, made from ripe berries of the American dwarf palm) is the botanical that is most used for symptoms of BPH and most studied in clinical trials. In the 2007 national survey on Americans' use of CAM, among respondents who used natural products as CAM, about 5 percent used saw palmetto (translating to about 1.7 million Americans).

Basic research on saw palmetto in laboratory and animal studies has

revealed some findings, such as the following, that may be relevant to its potential application in treating BPH:

- Saw palmetto appears to contain components that have activity similar to (but weaker than) 5-alpha-reductase inhibitors, which prevent conversion of testosterone to dihydrotestosterone.
- Saw palmetto contains substances, including certain fatty acids, that may have weak antiandrogenic effects as well as antiproliferative and anti-inflammatory properties.

## Snapshots of the Evidence

### Practice Guidelines

The American Urological Association's (AUA) evidence-based guideline on diagnosis and treatment of BPH—last updated in 2006 and currently being updated—recommends:

- For patients whose symptoms (as measured with a validated instrument such as the AUA Symptom Score Index) are mild or moderate, or who have severe symptoms that are not bothersome or do not interfere with daily activities of living, watchful waiting is preferred.
- For patients with bothersome moderate-to-severe symptoms, treatment options include watchful waiting and one or more of the following therapies: alpha-adrenergic blockers and 5-alpha-reductase inhibitors, separately or combined; minimally invasive therapies, such as transurethral microwave heat treatments or transurethral needle ablation; and, if earlier interventions have not resolved the problem, surgical treatment.

The AUA also states that phyto-therapeutic agents (i.e., plant-derived medications such as saw palmetto) and other dietary supplements cannot be recommended to treat BPH. Despite widespread use, their mechanisms of action, effectiveness, and safety have

not been sufficiently documented in high-quality clinical trials.

The 6th International Consultation on New Developments in Prostate Cancer and Prostate Diseases (held in 2005 and including AUA representation) focused on LUTS, including from BPH, in older men. This guideline recommends that only treatments with a strong evidence base for clinical effectiveness be used. With regard to “alternative treatments” (defined as consisting mostly of botanicals and polyene-derived agents), it notes that while progress has been made toward isolating components and identifying possible mechanism(s) of action, it is difficult to compare studies, and further research (including with long-term followup) is needed to draw conclusions.

### Systematic Reviews/Meta-Analyses

Findings from systematic reviews of saw palmetto for symptoms of BPH have been mixed, and the topic is an active area of debate. The number of trials available, especially randomized controlled trials (RCTs), is modest. Many earlier trials—in contrast to two more recent, better designed RCTs—have had issues that can affect the validity of findings, such as short duration, small size, and/or not having used standardized outcome measures.

### Cochrane Systematic Reviews

- A 2009 Cochrane review of 30 trials concluded that saw palmetto has little or no efficacy over placebo for treating BPH symptoms, although it appears to be safe. This conclusion changed from two earlier Cochrane reviews. Here, the review noted the availability of two better quality RCTs, one of which was also adequately powered. [The latter refers to the NCCAM-funded trial published in 2006, the largest and most rigorously designed study on this question to date, which found no improvement from saw palmetto,

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compared with placebo, in urinary symptoms and objective measures related to BPH.] The review found a certain amount of ambiguity in evidence on this topic and called for additional high-quality studies.

Other systematic reviews/meta-analyses include:

- A 2005 review on 38 studies (mostly on one commercial product), by the Natural Standard Research Collaboration, which concluded in favor of efficacy
- A 2002 meta-analysis on 17 published studies of a European commercial saw palmetto extract, by the European Institute of Oncology, which found suggestions of effectiveness over placebo on several measures in BPH symptoms.

Given the mixed research results, the high level of consumer interest in phytotherapeutic agents for BPH, and the remaining scientific questions, results are anticipated from a large RCT now under way—Complementary and Alternative Medicine for Urological Symptoms, or CAMUS. This trial is studying saw palmetto, compared with placebo, for preventing clinical progression of BPH over a longer term (18 months) than in earlier RCTs. CAMUS is taking place at 10 clinical centers, led by the University of Alabama at Birmingham. The National Institute of Diabetes and Digestive and Kidney Diseases, NCCAM, and the NIH Office of Dietary Supplements are the cosponsors.

### Safety

Saw palmetto is likely safe when used in typical doses, but more needs to be learned about its long-term safety and efficacy. Saw palmetto may cause mild side effects, typically gastrointestinal symptoms such as diarrhea. Some men who use saw palmetto have reported headache, dizziness, tender breasts, or reduction in sexual desire. There have been two case reports possibly linking saw palmetto to increased bleeding time and pancreatitis, but these reports have not been thoroughly researched. Since many of saw palmetto's purported active constituents are fat soluble, product forms that use water extraction (such as teas) might be less effective. For more on this botanical, go to [nccam.nih.gov/health/palmetto/](http://nccam.nih.gov/health/palmetto/).

### For More Information

- **National Center for Complementary and Alternative Medicine, NCCAM** Clearinghouse, [nccam.nih.gov](http://nccam.nih.gov); 1-888-644-6226 (toll free in the U.S.); 1-866-464-3615 (for deaf and hard-of-hearing callers).
- **National Institute of Diabetes and Digestive and Kidney Diseases**, [www.niddk.nih.gov](http://www.niddk.nih.gov).
- **The Cochrane Collaboration**, [www.cochrane.org](http://www.cochrane.org).
- **PubMed®**, [www.ncbi.nlm.nih.gov/sites/entrez](http://www.ncbi.nlm.nih.gov/sites/entrez).
- **CAM on PubMed®**, [nccam.nih.gov/research/camonpubmed](http://nccam.nih.gov/research/camonpubmed).
- **MedlinePlus**, [www.medlineplus.gov](http://www.medlineplus.gov).
- **ClinicalTrials.gov**, [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

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## New on the NCCAM Web Site: "Resources for Health Care Providers"

Get evidence-based information on CAM:  
Practice guidelines, CME, trials, databases, other resources.

[nccam.nih.gov/health/providers](http://nccam.nih.gov/health/providers)

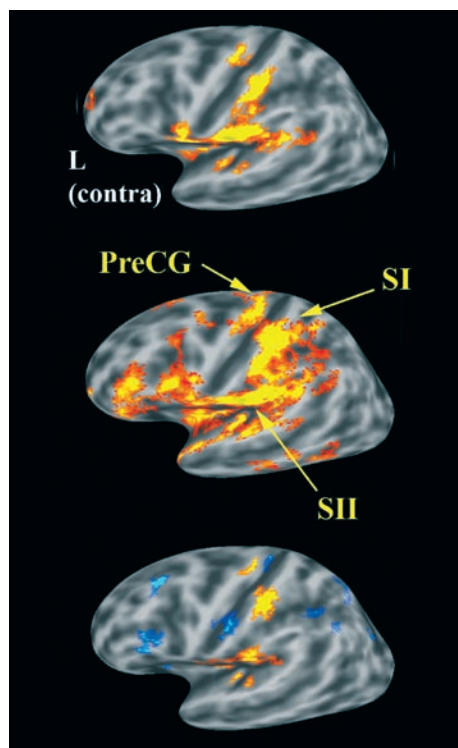


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## Advancing Research

“Our foremost achievement has been building the evidence base about CAM therapies,” Dr. Briggs said. “We have funded more than 2,200 research projects, resulting in more than 3,300 scientific articles published in peer-reviewed journals. More is now known about the efficacy and safety of CAM modalities, the biological mechanisms that underlie them, the methods and tools used to study them, and patterns of CAM use.”

NCCAM’s research ranges from basic science to real world effectiveness studies. “We are steadily building the evidence base, and the two key issues in the research are safety and efficacy. What I find particularly exciting is that we have increasing evidence that some CAM interventions can contribute to symptom management, especially management of pain. “Based on the growing evidence base for CAM interventions, a number of medical professional organizations—such as the American College of



A study led by Vasily Napadow, Ph.D., at the Martinos Center for Biomedical Imaging, Massachusetts General Hospital, Boston, examined the effects of acupuncture in patients with carpal tunnel syndrome. In these participants, nonpainful stimulation of finger 3 on the right hand produced hyperactivation in the left primary sensorimotor cortex. After acupuncture, this hyperactivity was reduced.

Physicians, the American Academy of Orthopaedic Surgeons, and the American Academy of Pediatrics—have included CAM modalities in recent guidelines.”

A number of major clinical trials have had implications for care of patients with common medical conditions. As one example, a randomized trial of acupuncture released earlier this year (more at [nccam.nih.gov/research/results/spotlight/062109.htm](http://nccam.nih.gov/research/results/spotlight/062109.htm)) found that people suffering from chronic low-back pain who received acupuncture or simulated acupuncture treatments fared better than those receiving only conventional care. “The fact that both these treatments can elicit positive responses,” said Dr. Briggs, “adds to the growing body of evidence that there is something meaningful taking place during acupuncture treatments outside of actual needling. Future research is needed to delve deeper into this question.”



Ginkgo biloba

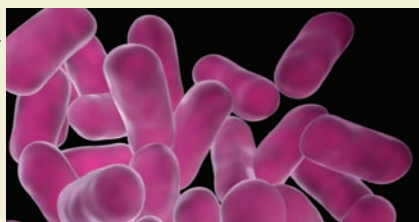
A major randomized study of Ginkgo biloba ([nccam.nih.gov/research/results/gems/](http://nccam.nih.gov/research/results/gems/)) found that the dietary supplement was ineffective in reducing the development of dementia and Alzheimer’s disease in participants age 75 or older with normal cognition or mild cognitive impairment. “This study also yielded information on subgroups that may be at greater risk for these conditions, and showed us that large clinical trials on dementia prevention can successfully be conducted in this population,” she said. A third trial studied the effects of glucosamine and chondroitin in a group of people with osteoarthritis of the knee ([nccam.nih.gov/research/results/gait/](http://nccam.nih.gov/research/results/gait/)). Its findings were mixed—the supplements combined did not provide

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## Examples of Areas of Research Promise

### Natural Products

- Molecular targets in small molecules in the diet, such as quercetins, curcumin, and other polyphenols and flavonoids
- Anti-inflammatory actions of omega fatty acids
- The effects of cranberry juice on bacterial adherence in the urinary tract



Lactobacillus acidophilus

- The effects of probiotics on the human microbiome

### Mind-Body Medicine

- Meditation and its effects on the regulation of emotion
- The importance of practitioner-patient interaction and health care context in the placebo response
- Therapies to help manage chronic pain, including:
  - How acupuncture and the placebo response engage endogenous opioid pathways to impact pain
  - Mind-body practices.
- Yoga and tai chi for improving balance and preventing falls in older adults

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significant relief from osteoarthritis pain among all participants, but were of benefit in a smaller subgroup with moderate-to-severe pain. “We also gained insights on the progression of osteoarthritis as well as predictors for which patients might respond best in future studies,” Dr. Briggs said. All three trials were cofunded with other NIH components: “Partnership is a strong theme for NCCAM.”



© Jeff Miller, University of Wisconsin-Madison  
Matthieu Ricard, Ph.D., a geneticist and Buddhist monk, is fitted with a “net” of electrodes in a study on meditation, led by Richard Davidson, Ph.D., University of Wisconsin-Madison.

### A Commitment to Research Training

When Congress established NCCAM, it sought to ensure that the Center would have a cadre of skilled investigators to carry out its research mission. Over its first decade, the Center has supported programs providing scientific research training and career development to students, CAM practitioners, conventional medical practitioners, and researchers.

For example, the Center has created a continuing education series on CAM on its Web site that offers CME/CEU credits to physicians and nurses ([nccam.nih.gov/training/videolectures/](http://nccam.nih.gov/training/videolectures/)). In 2008, NCCAM established the first NIH research training program expressly for CAM practitioners, cosponsored with The Bernard Osher Foundation and the Foundation for the National Institutes of Health.

### Outreach to the Public and Providers

“A crucial element of NCCAM’s mission is the dissemination of reliable and evidence-based information on CAM modalities. Only with this type of information can health care professionals and the public make informed decisions about the use of CAM and the integration of CAM with conventional medicine,” noted Dr. Briggs. She recommended that practitioners and the public bookmark the Center’s Web site—[nccam.nih.gov](http://nccam.nih.gov)—and visit it frequently to stay informed about the latest information on CAM. Among the Web site’s offerings are

- A new portal, “Resources for Health Care Providers” (see pg. 8)
- Fact sheets, research highlights, and other publications
- An education campaign, “Time to Talk,” to encourage open dialogue about CAM between health care providers and patients
- Information on special events, such as the Center’s 10th anniversary symposium on December 8, 2009 (see [nccam.nih.gov/news/events/anniversary\\_symposium.htm](http://nccam.nih.gov/news/events/anniversary_symposium.htm))
- Updates on NCCAM’s strategic planning process.

NCCAM also has an information clearinghouse with a toll-free number (see pg. 2) that responds to inquiries in English or Spanish, distributes NCCAM publications and selected other Federal publications on CAM, retrieves information from databases of scientific and medical literature, and makes referrals to other resources as appropriate. The clearinghouse does not provide medical advice or referrals to practitioners.

“With so many Americans using CAM—especially for self-care—and spending almost \$34 billion per year on CAM, NCCAM’s mission to rigorously study these therapies and communicate the findings to health care



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providers and their patients remains extremely important,” Dr. Briggs said. “Our information resources, which are rigorous and peer reviewed, are particularly important given that there is a lot of misinformation on the Web. We work to help educate the public to be more informed consumers, especially about the safety of dietary supplements.

“As we enter our second decade,” she concluded, “I am confident that NCCAM will continue to fulfill the charges set forth in its mission, applying the highest standards of scientific inquiry and investigation to ultimately help people make informed decisions about their health and health care.”

### Resources on NCCAM Research

Detailed information on results from trials supported by NCCAM is available on the NCCAM Web site at [nccam.nih.gov/research/results/](http://nccam.nih.gov/research/results/) and by searching CAM on PubMed, a subset of the National Library of Medicine’s PubMed database, at [nccam.nih.gov/research/camonpubmed/](http://nccam.nih.gov/research/camonpubmed/). A list of current NCCAM-supported clinical trials is at [nccam.nih.gov/research/clinicaltrials/](http://nccam.nih.gov/research/clinicaltrials/).



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## NCCAM Timeline— A Decade of Progress

**February 1999**—U.S. Congress establishes NCCAM as the 25th independent NIH unit.

**April 2002**—NCCAM's first large clinical trial shows that an extract of the herb St. John's wort is no more effective than placebo for major depression.

**December 2004**—Longest, largest randomized clinical trial of acupuncture ever conducted concludes it relieves pain and improves function for people with osteoarthritis of the knee and serves as an effective complement to standard care.

**February 2006**—Research shows that the popular dietary supplement combination of glucosamine plus chondroitin sulfate did not provide significant relief from osteoarthritis among all participants but did relieve moderate-to-severe pain among a subgroup of participants.

**June 2008**—NCCAM launches Time to Talk, first educational campaign.

**November 2008**—NCCAM's largest clinical trial to date, the Ginkgo Evaluation of Memory Study, finds the dietary supplement *Ginkgo biloba* does not delay development of dementia and Alzheimer's disease in older people.

**December 2008**—NCCAM releases new statistics on use of CAM among American adults and children from CDC's 2007 National Health Interview Survey.

**February 2009**—NCCAM marks its 10th anniversary.

*continued from 8*

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Natural medicines in the clinical management of benign prostatic hyperplasia.

## Complementary and Alternative Medicine: Focus on Research and Care

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## CAM and Integrative Medicine: A Decade of Growth

- Nearly 40 percent of adults polled in the 2007 National Health Interview Survey reported using CAM in the previous 12 months, most often for relief of pain problems, including back, joint, and neck pain. For new data on Americans' spending on CAM, see pg. 4.
- CAM therapies are among the national priority areas for comparative effectiveness research listed in a 2009 report by the Institute of Medicine of the National Academies, which also sponsored a summit on integrative medicine and the health of the public this year ([www.iom.edu/CMS/28312/52555.aspx](http://www.iom.edu/CMS/28312/52555.aspx)).
- Almost 40 percent of hospitals surveyed by the American Hospital Association in a 2007 national poll offered at least one CAM therapy. Among the reasons cited for including



*Reiki, an energy therapy that originated in Japan, is among hospital CAM offerings.*

CAM were an increasing prevalence of chronic illness, a need to treat conditions that often are not curable by conventional medicine, and increased patient demand for and satisfaction with CAM.

- Courses in CAM were a requirement in approximately 90 percent of medical schools in the United States for academic year 2007-2008, compared with 30 percent in 2001-2002, according to the Association of American Medical Colleges.
- The number of massage therapists and students doubled between 1996 and 2001, according to the American Massage Therapy Association. The Acupuncture and Oriental Medicine Alliance notes that the number of licensed acupuncturists in the United States nearly tripled from 1992 to 2004.
- Membership in the Consortium of Academic Health Centers for Integrative Medicine (see pg. 2) has grown from 11 members in 2002 to 42 today.

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## Reader Survey: NCCAM Newsletter

We value your comments on our redesigned newsletter, *Complementary and Alternative Medicine: Focus on Research and Care* (formerly *CAM at the NIH: Focus on Complementary and Alternative Medicine*). Please help us by taking a few minutes to answer the questions below. This NCCAM-sponsored survey is anonymous, and we cannot identify you (see [www.nih.gov/about/privacy.htm](http://www.nih.gov/about/privacy.htm)). Participation is voluntary, and you may decline to answer any or all of the questions.

To respond, just drop this postage-paid form in the mail.  
We'd like to hear from you by **January 2, 2010**. Thank you!

### 1. Please rate how much you agree with the following statements:

	Strongly agree	Agree	Disagree	Strongly disagree
The newsletter provides information that is useful and valuable to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I find the content easy to read.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I like the newsletter's design and format.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### 2. How interesting and useful do you find the following topics or features?

	Very interesting and useful	Interesting and useful	Not interesting and useful	N/A, do not read
Topics related to CAM in medical practice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Topics related to research on CAM	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Topics related to NCCAM and NIH	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Interviews with medical or scientific experts on CAM	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
"From the Director" column	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
"Get the Facts" articles for consumers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Coverage of major meetings on CAM	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Opportunities to apply for research funding	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Announcements of major grant awards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### 3. How interested are you in reading more about the following topic areas?

	Very interested	Interested	Not interested
General information on CAM therapies	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CAM treatments for specific conditions/illnesses	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Integrative medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Information on interpreting research studies and their results	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
News from NCCAM and NIH	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### 4. Are there other topics you would like to read about? If so, please specify:

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### 5. How would you prefer to receive the newsletter?

- ☐ PDF by e-mail
- ☐ Completely Web-based in HTML format
- ☐ Hard copy sent to me by postal mail
- ☐ Other format (please specify):

### 6. Do you share the newsletter with others?

- ☐ Yes
- ☐ No

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TEAR HERE

**7. Which of the following best describes you? (Select only one.)**

- ☐ Patient
- ☐ Family or friend of a patient
- ☐ Public
- ☐ CAM practitioner
- ☐ Other health care provider
- ☐ Researcher or grant applicant
- ☐ Journalist/media professional
- ☐ Student
- ☐ Other (specify):

**8. If you are a CAM practitioner, please indicate your specialty:**

- ☐ Chiropractic
- ☐ Traditional Chinese medicine, including acupuncture
- ☐ Naturopathy
- ☐ Homeopathy
- ☐ Massage therapy
- ☐ Energy medicine
- ☐ Other (specify):

**9. If you are another type of health care provider, please specify:**

- ☐ M.D. or D.O.
- ☐ Nurse
- ☐ Nurse practitioner
- ☐ Physician assistant
- ☐ Other (specify):

**Thank you again.** If you wish to provide further comments, please e-mail them to [info@nccam.nih.gov](mailto:info@nccam.nih.gov) or write to the NCCAM Clearinghouse, P.O. Box 7923, Gaithersburg, MD 20898-7923.

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